

## REMARKS

Claims 1 to 13 and 21 to 40 are in this application. Claims 14 and 41 to 50 have been cancelled. Claims 10, 11, 12 and 13 have been amended as proposed by the Examiner. Therefore, it is respectfully requested that the rejection of the claims under 35 USC 112, second paragraph and the objection to claims 12 and 13 be withdrawn.

The Examiner has provisionally rejected claims 1, 12, 13, 31 and 41 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 6, 8, 11-14, 17, 18, 20, 22-24, 63, 64, 67, 68, 70, and 72-74 of US patent application 09/896,903. A terminal disclaimer is attached. Therefore, it is respectfully requested that this rejection be withdrawn.

The Examiner has rejected claims 13, 14 and 31-50 as not being enabled. Applicants respectfully traverse this rejection.

Applicants submit that claims 13, 14 and 31-50 are enabled. In support thereof, applicants incorporate by reference the arguments and the declaration previously filed in this application.

The application discloses that the peptides of SEQ ID Nos. 3-12 are cytotoxic to one or more of the following cancer cell lines: colon, lung, prostate, stomach, laryngeal, oral, breast, duodenum, ovarian or pancreatic or leukemia or glioblastoma. The types of cancer in claims 13 and 31 to 40 are limited to these types and thus the scope of the claims is not overly broad.

Applicants have submitted the declaration of Rama Mukherjee showing that a peptide of this invention treats cancer *in vivo*. Applicants have also filed references which establish the correlation between *in vitro* and *in vivo* activity.

As stated in MPEP 2164.02 only an enabling disclosure is required and applicant need not describe all actual embodiments. In addition, as stated in this MPEP section, "An *in vitro* or *in vivo* animal model example in the specification, in

effect, constitutes a "working example" if that example "correlates" with a disclosed or claimed method invention. In this regard, the issue of "correlation" is also dependent on the state of the art. In other words, if the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlating unless the examiner has evidence that the model does not correlate. Even with such evidence, the examiner must weigh the evidence for and against correlation and decide whether one skilled in the art would accept the model as reasonably correlating to the condition. *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995). "

This MPEP section also provides that "A rigorous or an invariable exact correlation is not required, as stated in *Cross v. Iizuka*, 7523 F.2d 1040, 1050, 224 USPQ 739,747 (Fed. Cir.1985):

Based upon the relevant evidence as a whole, there is a reasonable correlation between the disclosed *in vitro* utility and *in vivo* activity, and therefore, a rigorous correlation is not necessary where the disclosure of pharmacological activity is reasonable based upon the probative evidence.

In addition it established law that "a patent need not teach, and preferably omits what is well known in the art." It is well known to use *in vitro* models to test compounds for anticancer activity and that one skilled in the art knows how to use these test results for *in vivo* treatment.

Applicants submit that claims 13, 14 and 31-50 are enabled. However, to expedite prosecution, applicants have cancelled claims 14 and 41-50. Applicants preserve all rights to file claims for this subject matter either in this application or divisional, continuation or continuation-in-part application.

Therefore, since the claims are enabled it is respectfully requested that this rejection be withdrawn.

Applicants submit that the present application is in condition for allowance

and favorable consideration is respectfully requested.

Respectfully submitted,

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